# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
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| S80760566:TPG:ph | | |
| International Application No. | International Filing Date *(day/month/year)* | Priority Date *(day/month/year)* |
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International Patent Classification (IPC) or national classification and IPC

Int. Cl.

| | | |
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| ***C07K 7/06*** (2006.01) | ***A61P 31/10*** (2006.01) | ***C12N 15/70*** (2006.01) |
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| ***A61K 38/16*** (2006.01) | ***C07K 14/37*** (2006.01) | |

Applicant

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1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheet(s).

3. This report contains indications relating to the following items:

| | | |
|---|---|---|
| I | [X] | Basis of the report |
| II | [ ] | Priority |
| III | [ ] | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | [ ] | Lack of unity of invention |
| V | [X] | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | [ ] | Certain documents cited |
| VII | [ ] | Certain defects in the international application |
| VIII | [X] | Certain observations on the international application |

| Date of submission of the demand | Date of completion of the report |
|---|---|
| 20 April 2005 | 27 January 2006 |
| Name and mailing address of the IPEA/AU | Authorized Officer |
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
**PCT/AU2004/001430**

## I. Basis of the report

1. With regard to the **elements** of the international application:*

- [ ] the international application as originally filed.
- [X] the description, pages **1-25,** as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [X] the claims, pages , as originally filed,
  pages , as amended (together with any statement) under Article 19,
  pages , filed with the demand,
  pages **26, 27,** received on **20 April 2005** with the letter of **20 April 2005**
- [X] the drawings, pages **1/4-4/4,** as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [X] the sequence listing part of the description:
  pages **1, 2,** as originally filed
  pages , filed with the demand
  pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [ ] the language of publication of the international application (under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- [X] contained in the international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form.
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages
   - [ ] the claims, Nos.
   - [ ] the drawings, sheets/fig.

5. [X] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | **1-19** | **YES** |
| | Claims | | **NO** |
| Inventive step (IS) | Claims | **1-19** | **YES** |
| | Claims | | **NO** |
| Industrial applicability (IA) | Claims | **1-19** | **YES** |
| | Claims | | **NO** |

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 STN File CA, Abstract 136:130418
D2 STN File CA, Abstract 135:29830

D1 and D2 disclose the expression of an antibacterial polypeptide LCI secreted by a *Bacillus subtilis* strain. The sequence consists of 47 residues, with the 30 N-terminal residues having the same sequence as the peptides of current SEQ ID NOs:1-3.

D1 and D2 both disclose the polypeptide LCI as having antibacterial properties, with D2 further suggesting use of the polypeptide as an antibacterial agent in plant breedings or bacterial fertilizer. There is no indication of use as an anti-fungal for the treatment of tinea, so that claims 1-19 fulfil the requirements of novelty and inventive step.

The current claims relate to methods of treatment of tinea, methods of controlling the growth of tinea-causing fungi and pharmaceutical compositions, therefore they are industrially applicable.

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

(i) Claims 1, 11, 12 and their dependent claims are not clear because it is not clear that the fungus being contacted with the peptide is a tinea-causing fungus.

(ii) Claim 3-5 are not clear because it is not clear whether the carbohydrate, lipid or alkyl are moieties on the peptide or are additional components i.e. separate molecules.

**Supplemental Box**
(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of Box I, item 5**

Claims 20 and 21 are considered to go beyond the disclosure as filed. These claims are to the use of a nucleic acid in the manufacture of a medicament for the treatment of tinea and whilst there is disclosure of the use of the peptides encoded by the nucleic acids in the manufacture of a medicament, there is no disclosure of the use of the actual nucleic acids in this manner.

## CLAIMS

1. (Amended) A method for controlling the growth of a fungus that is capable of causing tinea including contacting a fungus with a peptide having a sequence shown in any one of SEQ ID No.s: 1 to 3.

2. (Amended) A method according to claim 1 wherein the peptide has molecular weight of between about 750 and 1700 daltons.

3. (Amended) A method according to claim 1 wherein the peptide further includes a carbohydrate.

4. (Amended) A method according to claim 1 wherein the peptide further includes a lipid.

5. (Amended) A method according to claim 1 wherein peptide further includes an alkyl.

6. (Amended) A method according to claim 1 wherein the peptide includes a further domain for controlling the degradation of the peptide.

7. (Amended) A method according to claim 1 wherein the peptide is produced by expression of a nucleic acid.

8. (Amended) A method according to claim 7 wherein the nucleic acid has a sequence shown in any one of SEQ ID No.s: 4 to 8.

9. (Amended) A method according to claim 1 wherein the fungus is selected from the group of genera consisting of Trichopyton, Microsporum and Epidophyton.

10. (Amended) A method according to claim 9 wherein the fungus is selected from the group of species consisting of T. tonsurans, M. canis, M. auclounii and T. mentagrophytes.

11. (Amended) A method for controlling the growth of a fungus that is capable of causing tinea including contacting a fungus with a peptide having a sequence that is at least 75% homologous to a sequence shown in any one of SEQ ID No.s: 1 to 3.

12. (Amended) A method for controlling the growth of a fungus that is capable of causing tinea including contacting a fungus with a fusion protein including a peptide having a sequence shown in any one of SEQ ID No.s: 1 to 3.

13. (Amended) A method for treating an individual for tinea including administering to the individual, a peptide having a sequence shown in any one of SEQ ID No.s: 1 to 3.

14. (Amended) A method according to claim 13 wherein the tinea is tinea capitis.

15. (Amended) A method according to claim 13 wherein the tinea capitis is associated with a fungus selected from the group of species consisting of T. tonsurans, M. canis, M. auclounii and T. mentagrophytes.

16. (Amended) A method according to claim 13 wherein the peptide is administered to the individual by topical administration.

17. (Amended) A method according to claim 16 wherein the peptide is administered to the individual as a composition further including a solid, semi solid or liquid vehicle.

18. (Amended) A method according to claim 17 wherein the composition is selected from the group consisting of a solid, semi solid or liquid.

19. (Amended) Use of a peptide having a sequence shown in any one of SEQ ID No.s: 1 to 3 in the manufacture of a medicament for the treatment of tinea.

20. (Amended) Use of a nucleic acid encoding a peptide having a sequence shown in any one of SEQ ID No.s: 1 to 3 in the manufacture of a medicament for the treatment of tinea.

21. (Amended) Use according to claim 20 wherein the nucleic acid has a sequence shown in any one of SEQ ID No.s: 4 to 8.